

FSMA Preventive Controls for Animal Food

**Kelly Davis
Director of Regulatory Affairs
Renewable Fuels Association**

October 2016

About the Renewable Fuels Association

- ▶ Founded in 1981
- ▶ National Trade Association representing U.S. ethanol producers promoting policy, regulations, research and development for the industry
- ▶ Offices in Washington D.C. and St. Louis, Missouri
- ▶ Leader in legislative efforts of industry
- ▶ Encouraging safe practices throughout the industry
- ▶ Trusted source of scientific and technical expertise to support decision-making



**Mission: To drive expanded production and use of
American-made renewable fuels and bio-products worldwide**

Significant Animal Food Laws and Regulations

- 1906 Pure Food & Drug Act
- 1938 Federal Food, Drug & Cosmetic Act
- 1958 Food Additives Amendment
- 1976 Medicated Feed CGMPs
- 1996 Animal Drug Availability Act (VFDs)
- 1997 BSE/Ruminant Feed Regulations
- 2002 Bioterrorism Preparedness and Response Act
- 2007 Food and Drug Administration Amendments Act
- 2011 Food Safety Modernization Act (FSMA)
- 2014 Veterinary Feed Directive Revised Regulations

FSMA: Preventive Controls for Animal Food Timeline

- January 2011: FSMA signed into law
- October 2013: First version issued (Proposed Rule)
- September 2014: Second version issued (Revised Rule)
- September 2015: Final rule published

Business Size	<u>Subpart B</u> Current Good Manufacturing Practice	<u>Subpart C</u> Hazard Analysis and Risk-Based Preventive Controls
All Others	Sept. 19, 2016	Sept. 18, 2017
Small Businesses (< 500 FTE)	Sept. 18, 2017	Sept. 17, 2018
Very Small Businesses (< \$2.5 million/year)	Sept. 17, 2018	Sept. 17, 2019

FSMA Snap Shot

- The current food safety system has opportunity for improvement
 - 1 in 6 Americans (48 million) sickened, 128,000 hospitalized, 3,000 die each year from foodborne diseases (CDC, 2011)
 - Identified by FDA as the most sweeping reform of food safety laws in more than 70 years
- GOAL: Aims to ensure the U.S. food supply is safe by shifting the focus of federal regulators from responding to contamination to preventing it

21 CFR Part 507 – Preventive Controls for Animal Food

- Subpart A – General Provisions
- Subpart B – Current Good Manufacturing Practice
- Subpart C – Hazard Analysis and Risk-Based Preventive Controls
- Subpart D – Withdrawal of a Qualified Facility Exemption
- Subpart E – Supply-Chain Program
- Subpart F – Requirements Applying to Records That Must Be Established and Maintained

Who Must Comply?

- Facilities that manufacture, process, pack, or hold animal food for consumption in the United States
 - In general, those that register under Section 415 of the Federal Food, Drug, and Cosmetic Act (Bioterrorism Act)
 - Not complying is considered a prohibited act
- Animal food covered by specific CGMP regulations must still comply with those regulations
 - Low-acid canned food / Medicated feed
- Applies to domestic and imported food for animals
- Our industry examples; DDGS, Wet Distillers Grains, Corn Distillers Oil

Food Safety Modernization Act

The final rule implements Current Good Manufacturing Practices and the requirements for covered facilities to establish and implement a facility specific food safety system that includes a hazard analysis and risk-based preventive controls

- Specifically, the rule establishes requirements for:
 - A written food safety plan
 - Hazard analysis
 - Preventive controls
 - Monitoring
 - Corrective actions and corrections
 - Verification
 - Supply-chain program
 - Recall plan
 - Associated records

Current Good Manufacturing Practice (CGMPs)

Personnel

- Follow good hygiene practice
- Protection of food from contamination from personal effects

Plant and grounds

- Proper cleaning and maintenance of facility
- Pest control program
- Adequate restrooms
- Safe lighting, shatterproof glass or shields
- Adequate ventilation



CGMPs continued

Sanitation

- Includes maintaining clean and sanitary conditions of food contact surfaces, proper use and storage of toxic cleaning compounds
- Pest Control
- Proper storage of garbage and trash

Water supply and plumbing

- Plant's water supply, plumbing, and toilet and hand-washing facilities are adequate
- Adequate drainage, proper sewage disposal
- No cross connections or backflow between waste water or sewage and process waters

CGMPs continued

Equipment and Utensils

- All plant equipment and utensils must be designed and of such material and workmanship to be adequately cleanable, and must be properly maintained
- Instruments and controls maintained



CGMPs continued

Plant operations

- All operations in the manufacturing /processing, packing, and holding of animal food (including operations directed to receiving, inspecting, transporting, and segregating) are conducted in accordance with the CGMPs
- Chemical, microbial, or extraneous-material testing procedures are used where necessary to identify sanitation failures or possible animal food contamination
- Raw materials and ingredients must be inspected to ensure that they are suitable for manufacturing/processing into animal food and must be handled under conditions that will protect against contamination
- Rework procedures

CGMPs continued

Holding and distribution

- Protect against contamination and minimize deterioration
- Proper labeling
- Transport vehicle inspection procedures prior to loading



Hazard Analysis and Risk Based Preventive Controls

- A facility must prepare, or have prepared, and implement a **written food safety plan** prepared by (or its preparation overseen by) a **preventative controls qualified individual**.
- Components of the plan must include;
 - Hazard Analysis as required
 - Preventive Controls
 - Supplier Chain Program
 - Recall Plan
 - Procedures for Monitoring the Implementation of the Preventive Controls
 - Corrective action procedures
 - Verification procedures

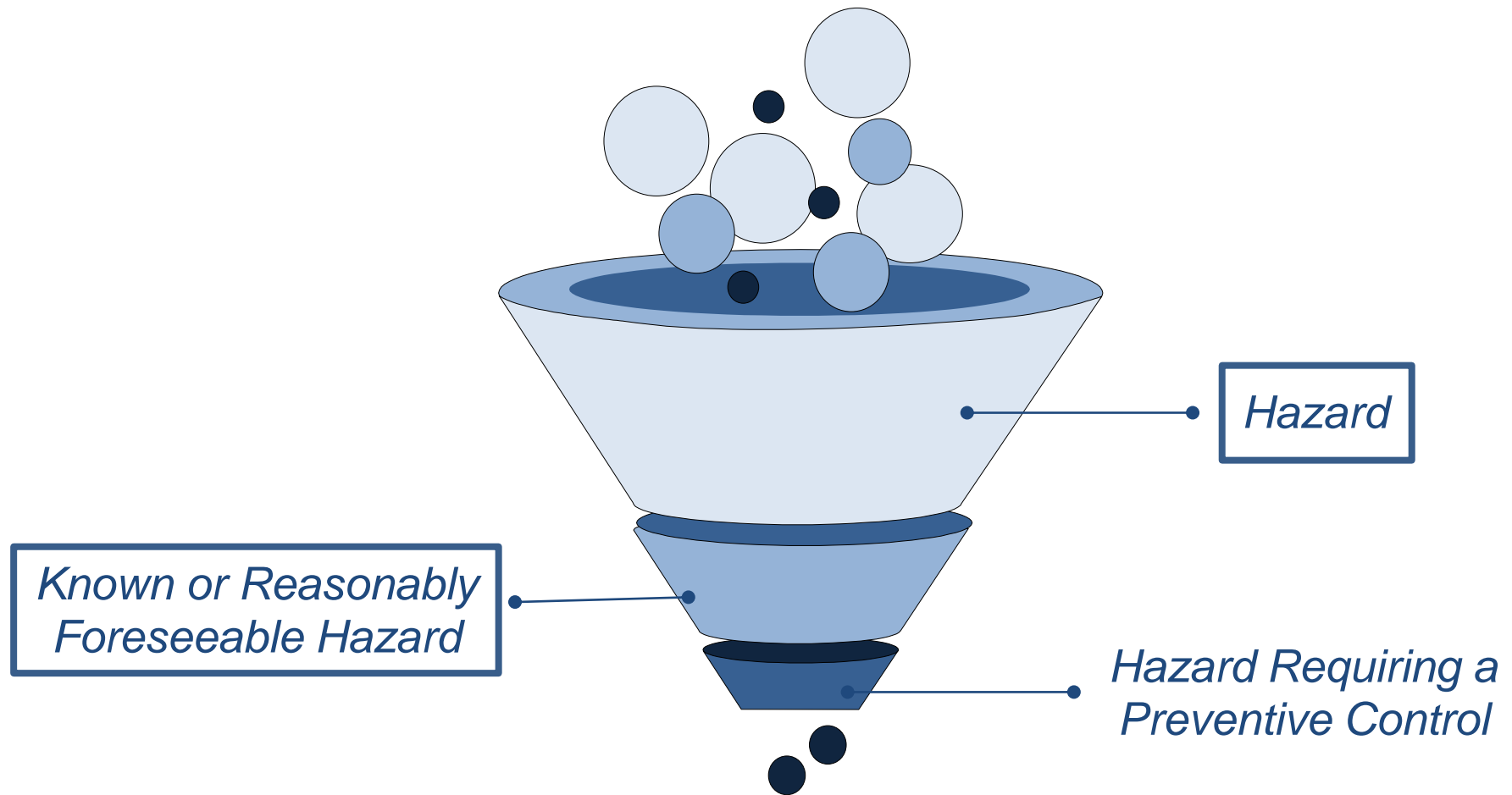
Hazard Analysis

- Identify and evaluate known or reasonably foreseeable hazards for each type of animal food manufactured /processed, packed, or held at your facility to determine whether there are hazards (facility specific)
- Hazards that include: Biological hazards, including microbiological hazards, chemical hazards, including radiological hazards, substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, nutrient imbalances and physical hazards
- Hazards may be present in the animal food for any of the following reasons:
 - The hazard occurs naturally;
 - The hazard may be unintentionally introduced; or
 - The hazard may be intentionally introduced for purposes of economic gain.

Hazard Analysis

- The hazard evaluation must consider the effect of the following on the safety of the finished animal food for the intended animal:
 - ✓ The formulation of the animal food;
 - ✓ The condition, function, and design of the facility and equipment;
 - ✓ Raw materials and other ingredients;
 - ✓ Transportation practices;
 - ✓ Manufacturing/processing procedures;
 - ✓ Packaging activities and labeling activities;
 - ✓ Storage and distribution;
 - ✓ Intended or reasonably foreseeable use;
 - ✓ Sanitation, including employee hygiene; and
 - ✓ Any other relevant factors such as the temporal (e.g., weather-related) nature of some hazards (e.g., levels of some natural toxins)

Hazard Analysis Process



Example Hazards in Animal Foods

- Biological hazards:
 - *Salmonella* spp.
 - *Listeria monocytogenes*
- Chemical hazards:
 - Mycotoxins
 - Pesticides and process-related or industrial chemicals
 - Drug carryover
 - Nutrient deficiencies or toxicities
- Physical hazards:
 - Stones
 - Glass
 - Metal

Process to Identify Hazards and Controls

Hazard Evaluation Examples


Critical



Moderate



Negligible

<div>SEVERITY</div> <div>PROBABILITY</div>		HIGH (I)	MEDIUM (II)	LOW (III)	VERY LOW (IV)
		Imminent and immediate danger of death or severe illness. Likely to impact humans and animals.	Danger and illness may be severe, but it is not imminent or immediate. Likely to impact animals, possible to impact humans.	Illness or injury may occur, but impact is reversible. Likely to impact animals, unlikely to impact humans.	Illness or injury is minor. Possible to impact animals, unlikely to impact humans.
HIGH (A)	Immediate danger that the hazard will occur.	I-A	II-A	III-A	IV-A
MEDIUM (B)	Probably will occur in time if not corrected.	I-B	II-B	III-B	IV-B
LOW (C)	Possible to occur in time if not corrected.	I-C	II-C	III-C	IV-C
VERY LOW (D)	Unlikely to occur; may assume hazard will not occur.	I-D	II-D	III-D	IV-D

Five point scale matrix Hazard Name Score Probability			Severity				
			Very High	Elevated	Medium	Low	Very low
			5	4	3	2	1
Description			Imminent and immediate danger of death or severe illness. Likely to impact humans and animals.	Danger and illness may be severe, but it is not imminent or immediate. Likely to impact animals, possible to impact humans.	Illness or injury may occur, but impact is reversible. Likely to impact animals, could impact humans.	Illness or injury is minor. Possible to impact animals, unlikely to impact humans.	Illness or injury is minor. Possible to impact animals, unlikely to impact humans.
High	5	Immediate danger that the hazard will occur.	25	20	15	10	5
Elevated	4	Probably will occur in time if not corrected.	20	16	12	8	4
Medium	3	Possible to occur in time if not corrected.	15	12	9	6	3
Low	2	Has occurred but rarely in limited cases	10	8	6	4	2
Very Low	1	Unlikely to occur; may assume hazard will not occur.	5	4	3	2	1

Five point scale matrix			Severity			Very High		Elevated		Medium		Low		Very low	
			Score			5		4		3		2		1	
			Description			Imminent and immediate danger of death or severe illness. Likely to impact humans and animals.		Danger and illness may be severe, but it is not imminent or immediate. Likely to impact animals, possible to impact humans.		Illness or injury may occur, but impact is reversible. Likely to impact animals, could impact humans.		Illness or injury is minor. Possible to impact animals, unlikely to impact humans.		Illness or injury is minor. Possible to impact animals, unlikely to impact humans.	
Probability			High	5	Immediate danger that the hazard will occur.	25	20	15	10	5					
			Elevated	4	Probably will occur in time if not corrected.	20	16	12	8	4					
			Medium	3	Possible to occur in time if not corrected.	15	12	9	6	3					
			Low	2	Has occurred but rarely in limited cases	10	8	6	4	2					
			Very Low	1	Unlikely to occur; may assume hazard will not occur.	5	4	3	2	1					

Mycotoxins - Ethanol Plant - case 1 Incoming corn			Severity 				
Score 			Very High	Elevated	Medium	Low	Very low
Description			5	4	3	2	1
Probability				Present certain years, swine performance depressed, dairy sensitive			
High	5	Spot testing, no records, some customer rejections		20			
Elevated	4						
Medium	3						
Low	2						
Very Low	1						

Mycotoxins - Ethanol Plant - case 2 Incoming corn			Severity 				
Score 			Very High	Elevated	Medium	Low	Very low
Description			5	4	3	2	1
Probability				Present certain years, swine performance depressed, dairy sensitive			
High	5						
Elevated	4						
Medium	3						
Low	2	Consistent composite testing of inbound and outbound, records since 2012, no customer reports		8			
Very Low	1	Testing is variable; can never assume zero incidence					

Hazard Analysis and Preventive Controls Determination Summary

- The hazard analysis is the most important element of developing an effective Food Safety Plan
- Hazard analysis includes identification, evaluation (for both severity and probability), and determination of control measures
- Outside resources can be utilized if needed to identify appropriate hazard analysis and control
- Hazard analysis is specific to the product and process

Preventative Controls

- Must identify and implement preventive controls, to provide assurances that significant hazards will be minimized or prevented and the animal food manufactured, processed, packed, or held by your facility will not be adulterated

Types of Preventive Control



Risk Based Preventive Controls continued

- **Perform preventive control management components**
 - **Monitoring procedures** that would provide assurance that preventive controls are consistently performed
 - **Corrective actions** that would be used if preventive controls are not properly implemented
 - **Verification activities** to ensure that preventive controls are consistently implemented and are effective.
Verification activities might include records review of monitoring, correction actions, or instrument calibration.
 - **Validation** of the preventative controls
 - **Verification of implementation and effectiveness** ;
calibrations, record reviews for product testing
 - **Reanalysis** of the food safety plan every three years
- **Recall plan** for animal food for which there are hazards that are reasonably likely to occur

Table 1. Hazard Analysis									
Identification			Evaluation				Preventive Control(s)		
(1)	(2)		(3)	(4)	(5)		(6)	(7)	(8)
List Ingredients and Steps/Equipment within the Process Flow	Identify <i>Known or Reasonably Foreseeable Hazards</i>		Assess Severity of Illness or Injury to Humans or Animals if the Hazard Were to Occur	Assess Probability that the Hazard Will Occur in Absence of Preventive Controls	PC Score	PC Needed	Justify the Classification for the Hazard in Step 5	Determine the Appropriate Control for any <i>Hazard Requiring a Preventive Control</i>	Assign a Preventive Controls Number
Corn-Receiving	B	Mycotoxins case 2	4	2	8	no	Matrix Above	NA	NA
	C								
	P								
Corn-Receiving	B	Mycotoxins case 1	4	5	20	Yes	Matrix Above	Weather monitoring, ramp up composite sample frequency for corn and ddgs, corn source id if needed	1
	C								
	P								

Case 1 would probably require a PC because there is not organized plan in place and documented already, either of inbound corn or outbound product.

Mycotoxins
case 1

Table 2. Description of Preventive Controls										
Preventive Control(s)					Management Components					
(1)	(2)	(3)	(4)	(5)	(6)				(7)	(8)
<i>Hazard Requiring a Preventive Control</i>	<i>Appropriate Control</i>	<i>Preventive Control Number</i>	<i>Preventive Control Category</i>	<i>Parameters (if applicable)</i>	<i>Monitoring (if applicable)</i>				<i>Corrective Action(s) and/or Correction(s)</i>	<i>Records</i>
					What	How	Frequency	Who		
Mycotoxins - Corn receiving	From above	1	Process	Corn: 8 ppb aflatoxin, 2 ppm vomitoxin. DDGS 20 ppb aflatoxin, 5 ppm vomitoxin.	Composite sample test results on grain and ddgs.	Control charts updated each test.	At frequency of composite testing, per sampling plan.	Merchandiser	Execute ramp-up testing plan, Selective marketing of DDGS.	Control charts, lab records

Supply-Chain Program

- The receiving facility must implement a risk-based supply-chain program for those raw materials and ingredients for which the receiving facility has identified a hazard requiring a supply-chain control
- The receiving facility is not required to establish and implement a supplier program for raw materials and ingredients for which:
 - There are no hazards
 - The preventive controls at the receiving facility are adequate to significantly minimize or prevent hazards
 - The receiving facility relies on its customer to control the hazard and annually obtains from its customer written assurance that the customer has established and is following procedures identified in the written assurance

Supply-Chain Program

- Use of approved suppliers
- Determine and conduct procedures for receiving and using raw materials and other ingredients
- Determination and conducting of the appropriate supplier verification activities for raw materials and other ingredients
- The program must provide assurance that a hazard requiring a supply-chain applied control has been significantly minimized or prevented

Records That Must Be Established and Maintained

Facility maintains the following records;

- written food safety plan, including the written hazard analysis, preventive controls, monitoring procedures, corrective action procedures, verification procedures, and recall plan
- records that document the monitoring of preventive controls
- records that document corrective actions
- records that document verification, including, as applicable, those related to validation; monitoring; corrective actions; calibration of process monitoring and verification instruments; records review; and reanalysis
- records that document applicable training for the qualified individual

Who is Responsible for Developing a Plan?

- A facility must prepare, or have prepared, and implement a written food safety plan prepared by (or its preparation overseen by) a **preventative controls qualified individual**
- PCQI performs
 - Preparation of the food safety plan
 - Validation of the preventive controls
 - Review of records
 - Reanalysis of the food safety plan (every three years minimum)

What are the Qualifications of Individuals?

- All individuals who manufacture/process/pack/hold animal food must be qualified to perform their assigned duties:
 - Includes temporary and seasonal workers
 - Must be a *Qualified Individual* as defined by § 507.3
 - Have education, training, experience, or a combination thereof, to complete duties in a way that results in safe food.
 - Receive training on animal food hygiene and safety, including importance of employee health and personnel hygiene as appropriate.
- The responsibility for this assurance changes:
 - Subpart B: Management of an establishment
 - Subpart C: Owner, operator, or agent in charge of the facility

Definition: “*Qualified Individual*”

- A person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold safe animal food as appropriate to the individual’s assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment.

Definition:

“Preventive Controls Qualified Individual”

- A Qualified Individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA, or is otherwise qualified through job experience to develop and apply a food safety system.

Animal Food Safety Preventive Control Alliance



- RFA participates in the Alliance with key industry, academic and FDA stakeholders helping develop a nationwide core curriculum, training and outreach programs to assist companies producing animal food in complying with the animal preventive controls regulations that are part of FSMA
- The Alliance developed the standardized training curriculum recognized by FDA

Animal Food Safety Preventive Control Alliance

- The Alliance is also developing commodity or industry sector-specific guidelines for animal preventive controls
- The example food safety plan for Distillers Products is currently in the review process
- Alliance intends on staying together to assess knowledge gaps and research needs for further enhancement of the animal preventive control measures

FSMA Training

- RFA provided training of the FDA / FSPCA 20-hour standardized course
- Lead instructors
 - Kelly Davis, RFA
 - Matt Frederking of Ralco Nutrition
 - Dr. Charles Hurburgh, Iowa State University professor-in-charge of the Extension-based Iowa Grain Quality Initiative
- Future Classes TBD

FSMA Training

- RFA organized classes in Omaha, Des Moines, Indianapolis and Minneapolis
- 70 companies now have Preventive Controls Qualified Individuals (PCQI) who can oversee the written food safety plan
- Ethanol industry is well prepared to supply safe animal food ingredients to the livestock industry per FSMA regulations

Thank you

